

General

Guideline Title

Indications of DXA in women younger than 65 yr and men younger than 70 yr: the 2013 official positions.

Bibliographic Source(s)

Malabanan AO, Rosen HN, Vokes TJ, Deal CL, Alele JD, Olenginski TP, Schousboe JT. Indications of DXA in women younger than 65 yr and men younger than 70 yr: the 2013 official positions. J Clin Densitom. 2013 Oct-Dec;16(4):467-71. [25 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Simonelli C, Adler RA, Blake GM, Caudill JP, Khan A, Leib E, Maricic M, Prior JC, Eis SR, Rosen C, Kendler DL. Dual-energy x-ray absorptiometry technical issues: the 2007 ISCD official positions. J Clin Densitom. 2008 Jan-Mar;11(1):109-22.

Recommendations

Major Recommendations

The definitions for quality of evidence (Good, Fair, Poor), strength of recommendations (A–C), and application of recommendations (W, L) are provided at the end of the "Major Recommendations" field.

Should Current National Osteoporosis Foundation (NOF) Guidelines That State That in Postmenopausal Women Younger Than 65 Yr a Bone Density Test Is Indicated if They Have an Additional Risk Factor for Low Bone Mineral Density (BMD) Be Retained?

Recommended Position Statement

Bone densitometry is indicated for:

- All women aged 65 yr and older
- Women younger than 65 yr if they have a risk factor for low bone mass, such as:
 - Low body weight
 - Prior fracture
 - High-risk medication use
 - Disease or condition associated with bone loss
- The Task Force recommended retaining the current approach of recommending BMD in postmenopausal women <65 yr if they have an
 additional risk factor for low BMD. Grade: Good-B-L

Should Current NOF Guidelines Be Retained for Which Patients among Men Aged 50 to 69 Yr, Is a Bone Density Test Indicated?

a. If not, what are the indications for a bone density test for men younger than 70 yr?

Recommended Position Statement

Bone densitometry is indicated for:

- All men aged 70 yr and older
- Men younger than 70 yr if they have a risk factor for low bone mass, such as:
 - Low body weight
 - Prior fracture
 - High-risk medication use
 - Disease or condition associated with bone loss
- Regarding men, the Task Force concluded that they should retain the current position to screen BMD for men ≥70 yr or sooner if they have
 a risk factor. The Task Force thought that men whose likelihood of osteoporosis was <10% could reasonably forego BMD, and the above
 criteria satisfy this requirement. Grade: Fair-B-L

Definitions:

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A: Strong recommendation supported by the evidence

B: Recommendation supported by the evidence

C: Recommendation supported primarily by expert opinion

Application of Recommendations

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Osteoporosis
- Osteopenia

Guideline Category

Diagnosis

Technology Assessment
Clinical Specialty
Endocrinology
Family Practice
Geriatrics
Internal Medicine

Radiology

Evaluation

Risk Assessment

Rheumatology

Intended Users

Obstetrics and Gynecology

Physicians

Guideline Objective(s)

- To update the 2007 International Society for Clinical Densitometry Official Positions guidelines for assessing bone density in younger women during and after the menopausal transition and in men 50-69 yr
- To reassess the National Osteoporosis Foundation (NOF) guidelines for ordering dual-energy x-ray absorptiometry (DXA) in postmenopausal women younger than 65 yr and men 50-69 yr
- To review the literature published since the 2007 Position Development Conference and 2008 NOF, reviewing clinical decision rules such as the Osteoporosis Screening Tool and the Fracture Risk Assessment Tool (FRAX)

Target Population

Women and men at risk of having low bone mass sufficient to warrant medical intervention

Interventions and Practices Considered

- 1. Dual-energy x-ray absorptiometry (DXA) for bone density testing (bone densitometry)
- 2. Risk factor assessment for bone densitometry in men and women

Major Outcomes Considered

- · Sensitivity and specificity of bone densitometry for bone mass sufficiently low to warrant treatment
- Fracture risk in men compared to women at the same absolute bone mineral density (in g/cm²)
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Task Force members performed a medical literature search relevant to the clinical and/or technical questions using a method modified from that utilized by the Cochrane reviews. The literature searches were conducted using electronic databases PubMed and MEDLINE, with search dates of 1/1/1990 through 1/31/2013. Appropriate articles were selected from the searches for further review.

Search terms included: bone mineral density plus reference data, bone mineral density plus normative data, bone mineral density plus NHANES, bone densitometry plus guidelines, bone densitometry plus guideline, dual energy x-ray absorptiometry plus guideline, dual energy x-ray absorptiometry plus guideline, bone densitometry plus indications, bone densitometry plus normative data, bone densitometry plus reference data, dual energy x-ray absorptiometry plus indication.

No specific inclusion or exclusion criteria were applied.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The development of the International Society for Clinical Densitometry (ISCD) Official Positions was undertaken according to the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM). This is a mechanism to determine whether procedures or indications are expected to provide a specific health benefit, designated as "appropriate," that exceeds the potential negative consequences by such a wide margin that the procedure or indication is worth doing, exclusive of cost. The rationale for use of the RAM for the Position Development Conference (PDC) is based on its ability to combine the best available scientific evidence with the collective judgment of worldwide experts in the bone field, to yield appropriate recommendations that are patient- and technology-specific.

Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

Description of Methods Used to Formulate the Recommendations

Position Development Conference (PDC) Expert Panel

Concurrent with Task Force work, international experts in the field of bone densitometry and societies specific to skeletal health were contacted by the PDC Steering Committee to serve as member panelists. Twelve experts agreed to participate on the PDC Expert Panel. In addition to individuals representing many regions of the world, one official representative from each of the following professional societies were participants on the expert panel: The American Society for Bone and Mineral Research (ASBMR), the North American Menopause Society (NAMS), and the National Osteoporosis Foundation (NOF). The role of the Expert Panel was to review the proposed Official Positions and supportive documents developed by the task forces and make final recommendations to the International Society for Clinical Densitometry Board of Directors (ISCD BOD).

PDC Moderators

PDC panel Moderators with experience in the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were selected by the Steering Committee. Two moderators assisted the Chair of the PDC in the development and refinement of statements derived from the initial Task Forces questions and sub-questions and, along with the Chair of the PDC, lead the discussion and the rating by the Expert Panel during the PDC in Tampa, Florida, USA.

Grading of the Official Positions

All Official Positions for the 2013 PDC were rated by the Expert Panel in the following categories: appropriateness, necessity, quality of evidence, strength of recommendations and application of recommendations (see the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields).

Proposed ratings in all cases, except the RAM ratings for appropriateness and necessity for each of the above categories, were included in the preliminary Official Positions crafted by each Task Force. Final ratings were determined by the on site meeting, convened Expert Panel that included appropriateness and necessity.

A rating of "appropriate" was required in order for a statement to be sent to the BOD for selection as an ISCD Official Position. Ratings of each Official Position from the 2013 PDC are expressed in the form of four characters representing quality of the evidence, strength of the recommendation, application of the recommendation, and whether it is necessary as previously described. For example, a rating "Good-A-W-Necessary" indicates that the evidence includes consistent results from well-designed, well-conducted studies in representative populations, a strong recommendation supported by the evidence, worldwide recommendation, and is necessary to perform in all instances. Since PDC topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the ISCD Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

PDC Procedures

After the initial selection of topics by the Board of Directors and Scientific Advisory Committee, the PDC Steering Committee selected three Task Force chairpersons, one for each of the three major PDC topics. Thereafter, the PDC Steering Committee and Task Force chairpersons worked collectively to select international experts as members of their respective Task Forces with the knowledge required to evaluate their assigned PDC topic. All topic questions and sub-questions that were generated by each Task Force were thoroughly researched in the scientific medical literature.

Prior to the PDC meeting in Tampa, Florida, USA, topic questions and sub-questions were converted into recommendation statements that were sent to the Expert Panel for an initial "appropriateness" rating. The PDC required a median "appropriateness" rating in either the upper third or lower third of the rating continuum (continuum was 1 to 9 with clusters 7 to 9 representing the upper third and clusters 1 to 3 representing the lower third) without "disagreement." "Disagreement" was defined as lack of consensus being predetermined to be four or more Expert Panelists rating in extreme clusters 1 to 3 and 7 to 9. In circumstances where the median "appropriateness" rating was less than 7, no Official Position was developed.

In making its decisions, the Expert Panel considered the level of the medical evidence, expert opinion, and the clinical need for a recommendation.

In some instances, regulatory issues received consideration. The statements rated as "appropriate" with a median score of 7 or higher without "disagreement" by the Expert Panel were designated Official Positions. The statements rated as "uncertain" with a median score between four and six or any median score with "disagreement" were further discussed at the PDC. After the initial rating the documents supporting all Task Forces' recommendations were sent to the Expert Panelists for review. In brief, Task Force chairs presented reports on their topics supporting the "uncertain" statements to the Expert Panelists in closed session on the first day of the conference. These statements were then edited by Task Force chairs, if necessary, reflecting suggestions made by the Expert Panelists. Re-rating of "uncertain" statements occurred during each Task Force chairpersons' presentation when the PDC Moderators felt there was a significant likelihood of change in the opinions of the Expert Panel.

After all statements rated as "appropriate without disagreement" had been selected and all supporting evidence presented, the Expert Panel performed a final rating for necessity, quality of the evidence, strength of the recommendation, and application of the recommendation. The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public (in conjunction with the ISCD Annual Meeting) and attended by ISCD members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the next day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Rating Scheme for the Strength of the Recommendations

All Official Positions for the 2013 Position Development Conference were rated by the Expert Panel in the following categories:

Appropriateness: Statements that the Expert Panel rated as "appropriate without disagreement" according to predefined criteria derived from the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were referred to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) with a recommendation to become ISCD Official Positions. A statement was defined as "appropriate" when the expected health benefit exceeded the expected negative consequences by a significant margin such that it was worth performing.

Necessity: Recommended Official Positions that were rated by the Expert Panel were then rated according to necessity to perform in all circumstances, i.e., whether the health benefits outweighed the risks to such an extent that it must be offered to all patients. Necessity rating was conducted in a similar fashion as the appropriateness rating, in that each Official Position had to be rated as necessary without disagreement using similar predefined RAM criteria.

Strength of Recommendations

A: Strong recommendation supported by the evidence

B: Recommendation supported by the evidence

C: Recommendation supported primarily by expert opinion

Application of Recommendations

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

Cost Analysis

- Prior studies have shown that bone densitometry followed by treatment of those with a prevalent vertebral fracture, femoral neck osteoporosis (T-score <-2.5), an absolute hip fracture risk of >3% (calculated using the Fracture Risk Assessment Tool [FRAX] algorithm) or an absolute major osteoporotic fracture (hip, spine, proximal humerus, or wrist) of >20% is cost-effective.
- The approach of screening men >70 yr was found to be cost-effective in one published study, and the prevalence of osteoporosis by bone mineral density (BMD) seems to be <10% until 70 yr in men.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public and attended by International Society for Clinical Densitometry (ISCD) members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the final day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Following completion of the Position Development Conference, the Steering Committee finalized recommendation wording without changing content. These recommendations were then presented to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) for review and voting. The BOD did not alter the content or wording of the proposed Official Positions. Recommendations approved by a majority vote of the ISCD BOD became ISCD Official Positions.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Since the field of bone densitometry is new and evolving, some clinically important issues that are addressed at the Position Development Conferences are not associated with robust medical evidence. Accordingly some Official Positions are based largely on expert opinion.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate detection of women and men with bone mass sufficiently low to warrant intervention
- Consistent diagnosis of osteoporosis by bone density criteria in both men and women

Potential Harms

Minor radiation exposure

Qualifying Statements

Qualifying Statements

- Since Position Development Conference topics are often selected because strong medical evidence is unavailable, it is the nature of the
 process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the International Society for
 Clinical Densitometry (ISCD) Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus
 attention on issues that require further study.
- For women, a previously published study gives the Task Force good data comparing the strengths and weaknesses of the different tools to
 predict low bone mineral density (BMD), but the Task Force has much less data about the comparative utility of these tools in men. The
 Task Force's position about not using the Fracture Risk Assessment Tool (FRAX) to determine which women should get a BMD before 65
 yr puts them at odds with the United States Preventive Services Task Force (USPSTF), which is an undesirable position. However, the
 data and good clinical judgment support the position they accepted.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy included publication of the International Society for Clinical Densitometry (ISCD) Official Positions in international journals that directly or indirectly pertain to skeletal diseases and the measurement of skeletal health.

Formal presentation of the ISCD Official Positions occurs at ISCD Annual Scientific Meetings, all ISCD Adult and Pediatric Bone Density Educational Courses, and ISCD Vertebral Fracture Assessment Educational courses. The Official Positions have been published in the society's official journal, *Journal of Clinical Densitometry and Assessment of Skeletal Health*.

Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Indications for dual-energy x-ray absorptiometry (DXA) were adapted in part from the following source:

 National Osteoporosis Foundation. 2013 Clinician's Guide to Prevention and Treatment of Osteoporosis. Washington, DC: National Osteoporosis Foundation. Source: http://nof.org/hcp/clinicians-guide

Date Released

2008 Mar (revised 2013 Oct-Dec)

Guideline Developer(s)

International Society for Clinical Densitometry - Nonprofit Organization

Source(s) of Funding

International Society for Clinical Densitometry

Guideline Committee

Indications for Bone Densitometry Task Force

Normative Databases for Bone Densitometry Task Force

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Financial Disclosures/Conflicts of Interest

None disclosed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Simonelli C, Adler RA, Blake GM, Caudill JP, Khan A, Leib E, Maricic M, Prior JC, Eis SR, Rosen C, Kendler DL. Dual-energy x-ray absorptiometry technical issues: the 2007 ISCD official positions. J Clin Densitom. 2008 Jan-Mar;11(1):109-22.

Guideline Availability

Electronic copies: Available to subscribers from the Journal of Clinical Densitometry Web site					
Print copies: Available from the International Society for Clinical Densitometry, 101 Centerpoint Drive, Suite 208, Middletown, CT 06457; Phone:					
(860) 259-1000; Fax: (860) 259-1030; Web site: www.jscd.org					

Availability of Companion Documents

The following are available:

•	2013 official positions of the International Society for Clinical Densitometry. 2013 Aug 15.	16 p. Electronic copies: Available from the
	International Society for Clinical Densitometry (ISCD) Web site	Chinese and Indonesian translations of the
	official positions are also available from the ISCD Web site	
•	Body composition analysis course. Available from the ISCD Web site	

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on July 24, 2009. The information was verified by the guideline developer on September 15, 2009. This summary was updated by ECRI Institute on August 21, 2014. The updated information was verified by the guideline developer on September 30, 2014.

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